

REMARKS

Claims 1-8 and 13-23 are all the claims pending in the application. New claims 22 and 23 have been added based on Example 4 and Figure 2 of the specification.

Entry of the above amendments is respectfully requested.

Initially, Applicants would like to thank the Examiner for the telephone interview conducted with Applicants' representative on April 29, 2010. Applicants believe that the interview was helpful in advancing the prosecution of the present application.

I. Response to Rejection of Claims 4 and 21 under 35 U.S.C. § 112, 1st paragraph

Claims 4 and 21 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants respectfully traverse the rejection.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See* MPEP § 2163.

An Applicant can show possession of the claimed invention is by describing the claimed invention with all of its limitations using descriptive means such as words, structures, figures, diagrams and formulas that fully set forth the claimed invention.

In this case, it is submitted that one of ordinary skill in the art would clearly recognize that Applicants were in possession of the claimed compound having specific X-ray crystalline positions recited in claims 4 and 21.

For example, the specification describes the present invention in the Disclosure of the Invention. In addition, the specification discloses how to make the compound having the specific X-ray crystalline positions, for example, in Example 4 on pages 21-24 of the

specification. Further, the melting point, IR spectra, and elemental analysis of the compound were measured.

In view of such disclosure, it is clear to one of skill in the art that claims 4 and 21 are adequately supported by the written description in the specification and comply with the requirements of 35 U.S.C. § 112, first paragraph.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

II. Response to Objection to the specification

The specification is objected to because it allegedly contains new matter.

Applicants respectfully traverse the objection.

It is submitted that the specification was amended to correct the name of the compound, and as such, the specification does not contain new matter.

Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

III. Response to Rejection of Claim 4 under 35 U.S.C. § 112, second and first paragraphs

Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

In addition, claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Applicants respectfully traverse the rejections.

Regarding the enablement rejection, it is submitted that the test is whether the disclosure in the specification is sufficient to enable one of ordinary skill in the art to practice the claimed invention without undue experimentation. The fact that experimentation is necessary is not conclusive of non-enablement but any necessary experiment should not be

undue. Further, a specification may be enabling without any working examples. *See* MPEP 2164.02.

In this case, as discussed above, the present specification describes the claimed compound of claims 4 and 21. In addition, the specification contains Example 4, which is a process for making the compound possessing the X-ray crystalline positions recited in claims 4 and 21.

In view of the disclosure, it is submitted that the specification does enable a person skilled in the art to make and/or use the invention, without undue experimentation.

Regarding the indefiniteness rejection, the Examiner states that there is no factual support that "the two enantiomers coexist as pairs in the same unit cell or the crystal lattice".

Applicants respectfully submit that such understanding is standard chemistry and that one of skill in the art would understand the meaning and scope of the claim.

It is submitted that one skilled in the art would understand that the compound of claim 4 is a racemic product. For instance, Example 4 uses commercially available DL-lactic acid to form raloxifene DL-lactate. In contrast, Examples 5 and 6 use L-lactic acid to form raloxifene L-lactate. It would be apparent to one skilled in the art that if the racemic lactic acid is used, a racemic product, with the two enantiomers coexisting in the same unit cell, would be formed, as in Example 4. Accordingly, it is submitted that claim 4 is definite.

For at least the foregoing reasons, withdrawal of the rejections is respectfully requested.

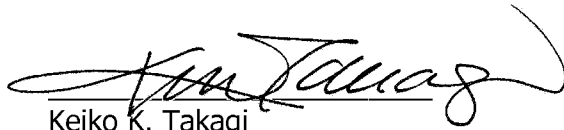
IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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